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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,081	09/12/2003	Benjamin J. Feldman	12008.32USD1	9809

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EXAMINER

NGUYEN, DONGHAI D

ART UNIT PAPER NUMBER

3729

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,081	Applicant(s) FELDMAN ET AL.	
	Examiner Donghai D. Nguyen	Art Unit 3729	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 18-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 December 2005 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1, 4, 5 and 18-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“the electrodes” (claim 1, line 5) is unclear and confusing in that it is not known as to which electrodes (counter, working or both electrodes) being overlaid by the spacer. Please clarify.

“a second substrate” (claim 24, line 12) is unclear and confusing in that it's not sure if it is as same as “a second substrate” as previously recited in lines 5-6).

Note: the volume unit “μL” (claims 1, line 9; claim 24, line 11; claims 23 and 27, lines 3; and claims 28 and 29, lines 3-4) should be changed to: --microliter-- for clarification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4, 5, 18-21, 23-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,708,247 to McAleer et al in view of US Patent 6,071,391 to Gotoh et al.

Regarding claims 1 and 23, McAleer et al disclose a method of manufacturing test sensor the method comprising: applying a plurality of working electrodes (14'/14) on a substrate (10); applying a plurality of counter electrodes (16/15) on the substrate; positioning a spacer layer (18) over the substrate and the counter and working electrodes; overlaying the spacer layer (18) with a second substrate (23); creating a sample chamber region (see Col. 3, lines 34-36) between the substrate having the electrodes and the second substrate (see, Figs. 1A and 2); and separating a plurality of, electrochemical sensors, each electrochemical sensor comprising at least one working electrode planar with at least one counter electrode, and at least one sample chamber region (Col. 6, lines, 15-17). McAleer et al do not teach the substrates having generally a similar length and width and the volume of the sample chamber region. Gotoh et al teach the substrates (see Col. 3, lines 62-65) each having generally a similar length and width (see Fig. 6) and the sample chamber region (8, see Gotoh's Fig. 3) having a volume of no more than about 1 microliter (0.5-10 microliter, see Col. 5, lines 37-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify invention of

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McAleer et al by utilize the substrates having similar length and with and the volume of the sample chamber region as taught and suggested by Gotoh et al (see Gotoh's Col. 1, lines 53-58) in order to obtain a desired sensor structure for measuring and analyzing of blood sample, etc. (Col. 2, lines 21-23).

Regarding claim 4, McAleer et al do not teach the adhesive. Gotoh's teach the adhesive (100-500 micrometer in thickness) over the substrate having the electrodes (See Col. 5, lines 51-57) for reducing cost in manufacturing the sensor (see Col. 2, lines 19-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of McAleer et al to utilize an adhesive layer for bonding the two substrates together as to by Gotoh et al.

The limitations of claims 5 and 20 are also met as set forth above.

Regarding claims 18 and 19, McAleer et al disclose the step of applying a plurality of working electrodes on a substrate by printing, screen printing or ink jet printing (See Col. 5, lines 53-67).

Regarding claims 24 and 27, McAleer et al disclose a method of manufacturing test sensor the method comprising: applying a plurality of working electrodes (14'/14) on a substrate (10); applying a plurality of counter electrodes (16/15) on the substrate; positioning a spacer layer (18) over the substrate and the counter and working electrodes; overlaying the spacer layer

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(18) with a second substrate (23); creating a sample chamber region (see Col. 3, lines 34-36) between the substrate having the electrodes and the second substrate (see, Figs. 1A and 2); and separating a plurality of, electrochemical sensors, each electrochemical sensor comprising at least one working electrode planar with at least one counter electrode, and at least one sample chamber region (Col. 6, lines, 15-17). McAleer et al do not teach the forming of indicator electrodes on one of the substrates, which having generally a similar length and width and the volume of the sample chamber region. Gotoh et al teach the forming of indicator electrodes (3 or 6) one of the substrates (see Col. 3, lines 62-65) each having generally a similar length and width (see Fig. 6) and the sample chamber region (8, see Gotoh's Fig. 3) having a volume of no more than about 1 microliter (0.5-10 microliter, see Col. 5, lines 37-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify invention of McAleer et al by the teaching of forming the indicator electrodes on one of the substrates having similar length and with and the volume of the sample chamber region as taught and suggested by Gotoh et al (see Gotoh's Col. 1, lines 53-58) in order to obtain a desired sensor structure for measuring and analyzing of blood sample, etc. (Col. 2, lines 21-23).

Regarding claims 21 and 25, McAleer et al disclose removing a portion (to expose the layer 16 and contact 11-13) of the spacer before the position it over the substrate having electrodes thereon (see Col.3, lines 34-36). Further, Gotoh et al also teach the removing a portion of the spacer (5 or 7, see Figs. 3 and 6).

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6. Claims 22, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al in view of Gotoh et al.

Regarding claims 22 and 26, McAleer/Gotoh et al do not disclose the removing a portion of the spacer after the step of disposing the spacer between the substrates. It would have been obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to remove a portion of spacer to form a sample chamber between the first and second substrates after the spacer being disposed between the substrates. Since Applicants have not disclosed that the particular portion of the spacer being removed after the disposing the spacer on the first or second substrate would require for a particular purpose, or solve a stated problem, and it appears that the invention would perform equally well with the teaching of the prior art and references (see McAleer Col. 6, lines 15-17 or Gotoh's Figs. 3 and 6).

Regarding claims 28 and 29 the prior arts do not teach the exact size of the sample chamber region such as 0.25 microliter. It would have been obvious matter of design choice to form the particular sample chamber region size and shape configurations as recited in claims 28 and 29. Since such modification such as change in size or shape involve a mere change in size of the component and is generally recognized as being within the level of ordinary skill in the art, etc., see *In Re Rose* 105 USPQ237 (CCPA 1995).

Response to Arguments

7. Applicant's arguments with respect to claims 1, 4, 5 and 18-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donghai D. Nguyen whose telephone number is (571)-272-4566. The examiner can normally be reached on Monday-Friday (9:00-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter D. Vo can be reached on (571)-272-4690. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DN
February 2, 2006


MINH TRINH
PRIMARY EXAMINER